

Non-steroidal Anti-inflammatory Drugs (NSAIDs)

Key Questions and Inclusion Criteria

Update #4

Key Questions

1. Are there differences in effectiveness between NSAIDs, with or without antiulcer medication, when used in adults with chronic pain from osteoarthritis, rheumatoid arthritis, soft-tissue pain, back pain, or ankylosing spondylitis?
 - a. How do oral drugs compare to one another?
 - b. How do topical drugs compare to one another?
 - c. How do oral drugs compare to topical drugs?
2. Are there clinically important differences in short-term harms (< 6 months) between NSAIDs, with or without antiulcer medication, when used in adults with chronic pain from osteoarthritis, rheumatoid arthritis, soft-tissue pain, back pain, or ankylosing spondylitis?
 - a. How do oral drugs compare to one another?
 - b. How do topical drugs compare to one another?
 - c. How do oral drugs compare to topical drugs?
3. Are there clinically important differences in long-term harms (\geq 6 months) between NSAIDs, with or without antiulcer medication, when used chronically in adults with chronic pain from osteoarthritis, rheumatoid arthritis, soft-tissue pain, back pain, or ankylosing spondylitis?
 - a. How do oral drugs compare to one another?
 - b. How do topical drugs compare to one another?
 - c. How do oral drugs compare to topical drugs?
4. Are there subgroups of patients based on demographics, other medications (e.g., aspirin), socio-economic conditions, co-morbidities (e.g., gastrointestinal disease) for which one medication is more effective or associated with fewer harms?

Inclusion Criteria

Populations: Adults with:

- Chronic pain from osteoarthritis
- Rheumatoid arthritis
- Soft-tissue pain
- Back pain
- Ankylosing spondylitis

Interventions

Oral Drugs (Trade names provided only for sole source drugs currently under patent)
--

- | |
|--|
| <ul style="list-style-type: none">• Celecoxib (Celebrex®) |
| <ul style="list-style-type: none">• Diclofenac potassium (Voltaren Rapide 50mg sugar coated tablet, * Zipsor® 25 mg liquid filled capsules **) |

• Diclofenac sodium
• Diflunisal
• Etodolac
• Fenoprofen (Nalfon® 400 mg capsules)**
• Flurbiprofen
• Ibuprofen
• Indomethacin
• Ketoprofen (Nexcede 12.5 mg oral film**)
• Ketoprofen XR,** Ketoprofen SR*
• Ketorolac
• Meclofenamate**
• Mefenamic acid
• Meloxicam
• Nabumetone
• Naproxen
• Naproxen delayed release,** Naproxen SR*
• Naproxen sodium
• Oxaprozin
• Piroxicam
• Salsalate**
• Sulindac
• Tenoxicam*
• Tiaprofenic Acid*
• Tolmetin**
Topical Drugs (Trade names provided only for sole source drugs currently under patent)
• Diclofenac epolamine 1.3% topical patch (Flector®)**
• Diclofenac sodium 1% topical gel (Voltaren®)**
• Diclofenac sodium 1.5% topical solution (Pennsaid®)
• Diclofenac sodium 3% topical gel (Solaraze®)**
• Topical diclofenac diethylamine 1.16% (Voltaren®, Emulgen™)*

*Only available in Canada

**Not available in Canada

Effectiveness outcomes

- Pain
- Functional status
- Discontinuations due to lack of effectiveness

Harms

- Serious GI events (GI bleeding, symptomatic ulcer disease, perforation of the GI tract, and death).
- Serious cardiovascular events (myocardial infarction, angina, stroke, transient

- ischemic attack, cardiovascular death, hypertension, congestive heart failure, and related measures).
- Tolerability and adverse event (e.g., discontinuation due to any adverse event; any serious adverse event; the overall rate of adverse events; the rate of GI adverse events; the combined rate of adverse events related to renal and cardiovascular function, including increased creatinine, edema, hypertension, or congestive heart failure; and the frequency of, and discontinuations due to, abnormal laboratory tests, primarily elevated transaminases)

Study designs

1. For effectiveness, controlled clinical trials and good-quality systematic reviews
2. For harms, controlled clinical trials, good-quality systematic reviews and observational studies